DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 16, 2015

Optos Plc.
% Mr. Randy Prebula
Partner
Hogan Lovells US, LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K142897
Trade/Device Name: P200DTx
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: MYC
Dated: December 17, 2014
Received: December 17, 2014

Dear Mr. Prebula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K142897

Device Name

P200DTx

Indications for Use *(Describe)*

The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina.It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(k) SUMMARY

Special 510k Summary:	Optos P200DTx Device
Name of Device:	P200DTx device
Common or Usual Name:	Scanning laser ophthalmoscope
Classification Name:	Scanning laser ophthalmoscope (per 21 C.F.R. § 866.1570)
Product Code:	MYC
Submitter:	Optos plc, Queensferry House, Carnegie Business Campus Dunfermline, Fife, KY11 8GR United Kingdom Phone: 011 44 1383 843300 Facsimile: 011 44 1383 843333
Contact Person:	Gunhild Paulsen
Date Prepared:	December 17, 2014
Predicate Device:	Optos Daytona ICG (P200TICG) and the Optos P200MAAF

Purpose of the Special 510(k) notice.

The P200DTx is a modification to the Daytona ICG (P200TICG) and the P200MAAF

Indications for Use

The P200DTx scanning laser ophthalmoscope is indicated for use as a widefield and retinal fluorescence and autofluorescence imaging ophthalmoscope to aid in the diagnosis and monitoring of diseases and disorders that manifest in the retina.It is also indicated for use as a widefield scanning laser ophthalmoscope for viewing choroidal circulation patterns that are illuminated using Indocyanine Green dye and for aiding in both the assessment of choroidal circulation and in the diagnosis of choroiditis or choroidal diseases.

Device Description

The Optos P200DTx is a scanning laser ophthalmoscope that uses lasers as a light source to illuminate the eye. The device consists of the following components and accessories:

- A scanhead which houses the lasers, the scanning elements of the light input path and the light return path including the detectors which convert light into electronic signal. The scanhead with its integral head and chin rest forms the key patient interface in conjunction with a facepad and associated aperture where the eye is placed. The image capture is

controlled by a computer and associated embedded software including a safety module within the scanhead. This software runs on a Linux operating system.

- A touchscreen is attached by a cable to the scanhead to assist the operator in optimal patient positioning and to initiate an image capture. An image is displayed on the screen to allow the operator to confirm a suitable image has been taken. Patient positioning and image capture can also be conducted via a hand control.
- A personal computer with a monitor to allow image review and storage in a Windows environment.

Device specifications, such as resolution, pixel density, angular field of view and minimum pupil size were base-lined on the predicate devices using in-house developed test targets.

Parameter	Specification
Optomap plus resolution	14um
Angular Field of View – external to eye	148 degrees x 115 degrees
Pixel Density	25 pixels/degree
Minimum pupil size	2mm
Patient Prescription Variation	+/- 12D

Principles of Operation and Technological Characteristics

The Optos P200DTx uses light that is scanned by a deflection system in two axes across the layers of the eye to generate an image. The returned light then travels back along the same path to a light detector that converts the light to an electrical signal. This electrical signal is digitized and used to build up an electronic picture in a computer and output on a display screen.

A summary of the safety system is as follows:

- Fast scan idle speed monitored. Power only supplied to beam delivery module if idle speed >7000rpm.
- Fast scan operating speed monitored. Laser enable only permitted if fast scan speed >30,000rpm
- Laser status monitored. Any conflict in laser status results in a system trip.
- Laser powers monitored. If laser power is outside 25% of the nominal power, the system will trip.
- Shutter status monitored. If conflict detected, system will trip.
- Line start rate monitored as back up to fast scan speed monitor (this detects that the light pulse is not static).

The fast scan and line start signals are implemented as low-voltage differential signalling (LVDS signals) to prevent failure occurring and all functionality is monitored on dual channels. All monitoring and decision making is implemented in two duplicated complex programmable logic devices (CPLD's) that must agree.

The layer of the eye viewed is determined by the wavelength of the laser utilized to illuminate the eye and the return path configured for the light either reflected and/or emitted by fluorescensce. For the P200DTx, the laser illuminating the eye can be:-

Infrared Light: the returned light is the fluorescence signal induced by the injection of indo cyanine green (ICG) dye. The detector used to capture this signal is optimized to detect infrared light and a filter is used to transmit only the fluoresced infra-red light which is at a slightly longer wavelength than the incident infra-red light entering the eye. This change in wavelength is a fundamental property of fluorescence.

Blue light: the returned light is the fluorescence signal induced by the injection of fluorescein dye. The detector used to capture this signal is optimized to detect light which is at a slightly longer wavelength than the incident blue light entering the eye and a filter is used to remove any reflected blue light of the same incident wavelength. This change in wavelength is a fundamental property of fluorescence.

Green light: the natural fluorescence of the retina can be imaged using a green wavelength. No dye injection is required for autofluorescence. The detector used to capture this signal is optimized to detect light which is at a slightly longer wavelength than the incident green light entering the eye and a filter is used to remove any reflected green light of the same incident wavelength. This change in wavelength is a fundamental property of fluorescence including autofluorescence.

Red and Green Light: a red and green light is used to illuminate the eye to obtain a non-fluoresced image. The incident and reflected light is at the same wavelength. A separate red and green or a composite image can be viewed.

Performance Data

Conformance to the device performance specifications was proven during verification testing using the same test targets as the cleared predicates. Tolerance to patient eye variation was tested using off the shelf commercial ray tracing software. In all instances, the Optos P200DTx device functioned and imaged as intended and substantial equivalence to predicate devices was established. As the P200DTx combines the imaging modes within the Daytona ICG and P200MAAF, the light input, output and required detector settings to convert the light to a digital image are known.

The P200DTx's compliance to electrical safety, light safety and biocompatibility has been established. The software development lifecycle and the associated verification & validation activities have no unresolved major or critical bugs.

A summary of the type testing supporting this is as follows:

Electrical Safety testing (general and electromagnetic compatibility)

The P200DTx device meets the requirements of AAMI ANSI 60601-1:2005 & A1:2012 which includes an assessment of the software development lifecycle process. There were no procedure deviations, no non-standard test methods were used and no additional testing deemed necessary.

The P200DTx is compliant to the specification IEC 60601-1-2 and 47 CFR Part 15 subpart B with no abnormalities or departures from the standard conditions.

IEC 60825 (Light Hazard standard)

The Optos device is class I to standard IEC 60825. Class I is the lowest, safest classification.

ISO 10993 (Biocompatibility)

As per ISO 10993-1 the contact is surface, intact skin for a limited duration (≤24 hours), requiring cytotoxicity, sensitization and irritation or intracutaneous reactivity. The patient contact points are the face pad, head rest and chin rest. The same material is used for all patient contact points.The results are tabulated as follows:-

Contact Points	**Test**	**Result**
Face pad, head and chin rest	Cytotoxicity test ISO 10993-5	Test article not considered to have cytotoxic potential
Face pad, head and chin rest	Tests for irritation and skin sensitization ISO 10993-10, intracutaneous injection	Test article sites did not show a significantly greater biological rate than control
Face pad, head and chin rest	Tests for irritation and skin sensitization ISO 10993-10, Kligman sensitization	A grade 1 sensitization rate is not considered significant and the test article meets the requirement

ISO 15004-2: Ophthalmic Instruments, light hazard protection: The device is a group 1 ophthalmic instrument.

The aperture height of the P200DTx has a very comparable range when compared to the P200MAAF predicate. The device angle from vertical of both the P200DTx and P200MAAF scanheads are similar. The amended device and the P200MAAF both utilize powered tables, XYZ stage and a head and chin rest. The P200DTx and P200MAAF both have a hand control.

Given these similarities in operability, an internal design validation confirmed the design realisation of this layout relating to the ability to capture an image.

Substantial Equivalence

The P200DTx device is as safe and effective as the predicate devices, the Optos Daytona ICG (K134039) and the P200MAAF(K102492)

The P200DTx has the same intended use and indications for use and similar principles of operation and technological characteristics as the predicate devices.

The predicate devices use the same lasers as the light source(s) and, depending on the wavelength, generates images based on reflectance or fluorescence based on the natural fluorescence of the eye or the induced fluorescence created by injection of a dye(s).

Similar to the Optos P200DTx, the predicate devices require the laser to be scanned horizontally and vertically and the returned light, whether fluoresced or reflected, is converted into an electronic signal by a detector for subsequent display on a screen.

The predicate devices are of similar construction and being an optomechanical electronic device utilizing a laser(s) is subject to the same general electrical, light hazard and software standards for

such medical electrical equipment. Additionally, both the Optos and predicate device are class I in terms of laser power at the eye as defined by IEC 60825 so both devices are dependent on comparable incident light levels to possess this functionality.

The minor technological differences between the P200DTx and the predicate devices do not raise any new questions of safety and effectiveness. Type test data and internal design validation demonstrates that the Optos P200DTx is as safe and effective as the Optos Daytona ICG (K134039) and the P200MAAF(K102492)

Thus, the Optos P200DTx Ophthalmoscope is substantially equivalent to legally marketed Optos Daytona ICG (K134039) and the P200MAAF(K102492)

Conclusions

The Optos P200DTx has similar characteristics as determined by electrical, light hazard and biocompatibility type testing. Additionally the testing conducted plus the comparable specifications for the light sources, returned light filtration and required detector light sensitivities demonstrate that the device is as safe, as effective, and performs as well as the predicate devices